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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/030,225 | 06/27/2002 | Toshio Ota | 084335-0153 | 9216 |

22428 7590 03/22/2005

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| EXAMINER |
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HUNNICUTT, RACHEL KAPUST

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| ART UNIT | PAPER NUMBER |
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1647

DATE MAILED: 03/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,225

Applicant(s)

OTA ET AL.

Examiner

Rachel K. Hunnicutt

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-6, 19-22 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-6, 19-22 and 24-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 0205.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Upon further consideration, the finality of the previous office action is withdrawn.

Applicant's amendment filed January 18, 2005 is acknowledged. Claim 1 is amended. Claims 2-3, 7-18, and 23 have been canceled. Claims 24-26 are new. Claim 23 is rejoined with claims 1, , 4-6, 19-21, and 24-26. Claims 1, 4-6, 19-22, and 24-26 are pending and under consideration. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections Withdrawn

The rejection of claims 1, 4-6, and 19-20 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in response to Applicant's amendment to the claims.

The rejection of claims 1, 4-6, and 19-20 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn in response to Applicant's amendment to the claims.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-6, 19-22, and 24-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 21, and 24 refer to "a polynucleotide comprising a protein-coding region of the nucleotide sequence *according to* SEQ ID NO: 1" or "a protein comprising the amino acid sequence *according to* SEQ ID NO: 2" or "the amino acid sequence

according to positions 27 to 213 of SEQ ID NO: 2” (emphasis added). The phrase “according to” is unclear in that it does not distinctly point out the invention. In order to obviate the rejection, the claims could be amended to read “a polynucleotide comprising a protein-coding region of the nucleotide sequence *of* SEQ ID NO: 1” or “a protein comprising the amino acid sequence *of* SEQ ID NO: 2”.

Claims 1, 4-6, and 19-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is drawn to “a polynucleotide comprising a protein-coding region of the nucleotide sequence according to SEQ ID NO: 1”. It is not clear whether “a protein-coding region” is meant to encompass only the region of SEQ ID NO: 1 that encodes SEQ ID NO: 2, or whether “a protein-coding region” is meant to encompass any part of SEQ ID NO: 1 that encodes any protein sequence. One skilled in the art would not know the scope of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by NCBI Accession No. AF111168 (Homo sapiens serine palmitoyl transferase, subunit II gene, January 26, 1999, submitted by Applicants in February 2005 IDS). Claim 1 is drawn to a polynucleotide comprising a protein-coding region of SEQ ID NO: 1. The protein-coding region is not limited to a particular region of SEQ ID NO: 1. NCBI Accession No. AF111168 is 100% identical to positions 140-279 of SEQ ID NO: 1 (positions 87530-87429 of AF111168) and positions 382-631 of SEQ ID NO: 1 (positions 87163-86914 of AF111168). Thus, claim 1 is anticipated by NCBI Accession No. AF111168 because the sequence comprises a protein-coding region of SEQ ID NO: 1.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1, 4-6, 19-22, and 24-26 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 24, 25, 29-31, 34-38, 47-52, and 54 (SEQ ID NOS: 153 and 154) of copending Application No. 10/305,278. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Conclusion

NO CLAIMS ARE ALLOWED.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel K. Hunnicutt whose telephone number is (571) 272-0886. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Art Unit: 1647

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RKH
3/18/05


JANET ANDRES
PRIMARY EXAMINER